(2)

Supreme Court, U.S.
FILED
FEB 24 2000
CLERK

No. 99-1034

In The

Supreme Court of the United States

CENTURY CLINIC, INC. and KATRINA TANG, M.D. and H.M.D.,

Petitioners,

-v-

UNITED STATES OF AMERICA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

---

REPLY BRIEF FOR PETITIONERS

Wm. Bradford Reynolds
(Counsel of Record)
Stephen Weissman
COLLIER, SHANNON, RILL
& SCOTT, PLLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
(202) 342-8400

Thomas C. Bradley
SINAI, SCHROEDER,
MOONEY
BOETSCH & BRADLEY
448 Hill Street
Reno, NV 89501
(702) 323-5178
Attorneys for Petitioners

32pp

PUBLISHER'S NOTE :

ORIGINAL PAGINATION IS NOT CONTINUOUS.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

REASONS FOR GRANTING THE WRIT 1

I. This Court's Review is Necessary to Resolve the Differences Among the Circuits, as Well as Within its Own Decisions, as to the Proof Required to Satisfy the "Clear and Convincing Evidence" Standard 1

II. The Court of Appeals Erred as a Matter of Law by Affirming an Administrative Finding of Contempt Based Exclusively on an Incomplete and Defective Tape Recording Created by an Agency Official whom Petitioners Could Not Cross-Examine 5

CONCLUSION 8

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Addington v. Texas, 441 U.S. 418 (1979) 4

Colorado v. New Mexico, 467 U.S. 310 (1984)) 4

Consolidation Coal Co. v. United Mine Workers, 514 F.2d 763 (6th Cir. 1975) 6

Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990) 4

D.H. Overmyer Co. v. Frick Co., 405 U.S. 174 (1972) ... 6

Disner v. Westinghouse Elec. Corp., 726 F.2d 1106 (6th Cir. 1984) 2, 3

Elliott Assocs., L.P. v. Republic of Peru, 12 F. Supp. 2d 328 (S.D.N.Y. 1998), rev'd on other grounds, No. 98-9268, 1999 U.S. App. LEXIS 26370 (2d Cir. Oct. 20, 1999) 4

First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938 (1995) 4

In re Medrano, 956 F.2d 101 (5th Cir. 1992) 4

Quinter v. Volkswagen of Am., 676 F.2d 969 (3d Cir., 1982) 3, 5

Travelhost, Inc. v. Blandford, 68 F.3d 958 (5th Cir. 1995) 3, 4, 5

United States Fire Ins. Co. v. Royal Ins. Co., 759 F.2d 306 (3d Cir. 1985) 4

United States v. Mendenhall, 446 U.S. 544 (1990) 2

United States v. Williams, 504 U.S. 36 (1992) 2

Virginia Bankshares, Inc. v. Sandberg, 501 U.S. 1083 (1991). 2, 3

Petitioners, Century Clinic, Inc. and Katrina Tang, M.D. and H.M.D., respectfully file this Reply to the Brief for the United States in Opposition ("Opp. Br.").

REASONS FOR GRANTING THE WRIT

I. This Court's Review is Necessary to Resolve the Differences Among the Circuits, as Well as Within its Own Decisions, as to the Proof Required to Satisfy the "Clear and Convincing Evidence" Standard

The Solicitor General offers several arguments in an attempt to defeat this Court's review of the important questions raised in Petitioners' opening brief. None of the arguments has merit.[1/]

1. The Solicitor General first contends (Opp. Br. at 4-5) that this Court should not resolve the conflict among the circuits, as well as within its own decisions, as to the appropriate definition of "clear and convincing evidence" because Petitioners failed to raise the issue in the court of appeals. The issue presented in this certiorari petition is, however, not so easily avoided. Petitioners *did in fact* raise the issue in the court below, seeking appellate review of the Food and Drug Administration ("FDA") Hearing Officer's contempt finding "in its entirety" (*see* Supp. Apdx. A, at 4), as the court of appeals specifically noted in its opinion (*see* Apdx., at 2a). It is not disputed that the Hearing Officer's

---

1/ The Solicitor General, perhaps due to an unfamiliarity with the record, misstates that, prior to 1993, Petitioners "used an unapproved medical device (an ohmmeter) to diagnose whether patients had various diseases" (Opp. Br. 2). As the record below shows conclusively, the assertion is untrue.

contempt finding, as affirmed by the courts below, was rooted in a "highly probable" definition of "clear and convincing evidence" (*see* Apdx., at 54a) -- a definition directly at odds with other federal courts' understanding and application of that evidentiary standard, especially in the context of civil contempt proceedings. *See* Pet. Opening Br., at 9-14. Petitioners' challenge to the Hearing Officer's application of the "clear and convincing evidence" standard was carried to the district court level (*see* Supp. Apdx. B, at 31), and was included in their Ninth Circuit appeal of the Hearing Officer's finding of contempt in its entirety. *See* Supp. Apdx. A, at 4; Supp. Apdx. C., at 14; Apdx., at 2a.

It is, moreover, well established that this Court considers questions of law that were *either* "pressed" *or* "passed upon" below. *See, e.g., United States v. Williams*, 504 U.S. 36, 41 (1992) ("Our traditional rule . . . precludes a grant of certiorari only when 'the question presented was not pressed or passed upon below'. . . . That this rule operates (as it is phrased) in the disjunctive, permitting review of an issue not pressed so long as it has been passed upon, is illustrated by some of our more recent dispositions."); *accord Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1099 n.8 (1991). The Hearing Officer's "highly probable" definition of "clear and convincing evidence" was both challenged (Supp. Apdx. B, at 31; Supp. Apdx. A, at 4) and "passed upon" (*id.*) below. Indeed, that issue was central to the court of appeals' disposition of the case. *See United States v. Mendenhall*, 446 U.S. 544, 551-52 n.5 (1990) (where the determination of a question "is essential to the correct disposition of the other issues in the case," the question has been raised); *cf. Disner v. Westinghouse Elec. Corp.*, 726 F.2d 1106, 1111 (6th Cir. 1984) (when a court permits a claim to be established by a degree of proof less than required by law, the entire disposition of the case is subject to reversal). Where, as here,

the appellate court passes on an issue of particular uncertainty and importance to the administration of law in federal courts, that issue is amply preserved for review by this Court. *See Virginia Bankshares*, 501 U.S. at 1099 n.8 ("It suffices for our purposes that the Court below passed on the issue presented, particularly where the issue is, we believe, in a state of evolving definition and uncertainty, and one of importance to the administration of federal law) (citations and internal quotation marks omitted). The issue is thus properly before this Court.

2. Presumably recognizing that the issue presented is not readily avoidable, the Solicitor General further contends that there is no need for Supreme Court review because the Hearing Officer's application of the "highly probable" standard in this contempt action was not "arbitrary or capricious." *See* Opp. Br., at 5-6. To the contrary, it is, we submit, indeed "arbitrary and capricious" for a Hearing Officer, hand picked by the FDA, to rest his finding of civil contempt on an incorrect and overly lenient definition of "clear and convincing evidence," especially where the federal courts apply a far more rigorous standard of proof in this very context.[2/] *See Disner*, 726 F.2d at 1111 (clear error exists when a decisionmaker "permits a claim to be established by a degree of proof less than required by law"). Review by this Court is needed to resolve this irreconcilable tension between the circuit courts as to the proper definition of "clear and convincing evidence" (*see* Pet. Opening Br., at 9-15), a tension that is reflected as

---

2/ *See* Pet. Opening Br., at 12-14, citing *Travelhost, Inc. v. Blandford*, 68 F.3d 958, 961 (5th Cir. 1995) (applying *Cruzan* definition in civil contempt action) and *Quinter v. Volkswagen of Am.*, 676 F.2d 969, 974 (3d Cir. 1982) (defining "clear and convincing evidence" in context of civil contempt proceedings as being satisfied only if there is not "ground to doubt the wrongfulness of the conduct of the defendant").

well in this Court's own decisions. *Compare Colorado v. New Mexico*, 467 U.S. 310 (1984) (utilizing "highly probable" standard), *with Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990) (adopting a more rigorous definition of "clear and convincing evidence"). *And see* Pet. Opening Br., at 9-15 (discussing the even more exacting "no reasonable doubt" standard).

The Solicitor General's Opp. Br. underscores the need for plenary review by this Court. It lamely argues that "[d]ifferent federal law issues may call for somewhat different formulations of what constitutes clear and convincing evidence." *See* Opp. Br., at 6. That is, of course, precisely why the writ should be granted. This Court has regularly admonished against proliferating and amorphous legal standards. *See e.g., First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 948 (1995) (noting that too many standards "make the law more complicated," and cautioning against the proliferation of judicial standards of review); *Addington v. Texas*, 441 U.S. 418, 423-45 (1979) ("adopting a 'standard of proof is more than an empty semantic exercise'").

Here, we have at least three options. There is the relaxed "highly probable" standard in *Colorado*. There is the more stringent "clear and convincing evidence" standard of *Cruzan* (downplayed to a fault by the Solicitor General, at Opp. Br. 5-6). *See, e.g., Travelhost*, 68 F.3d at 961; *In re Medrano*, 956 F.2d 101, 102 (5th Cir. 1992); *Elliott Assocs., L.P. v. Republic of Peru*, 12 F. Supp. 2d 328, 345 (S.D.N.Y. 1998), *rev'd on other grounds*, No. 98-9268, 1999 U.S. App. LEXIS 26370 (2d Cir. Oct. 20, 1999); *cf. United States Fire Ins. Co. v. Royal Ins. Co.*, 759 F.2d 306, 309 (3d Cir. 1985). And there is the even harsher "no reasonable doubt" definition accepted in several federal circuits. *See* Pet. Opening Br., at 13-14.

Guidance from this Court is thus needed. The affirmance below of the FDA Hearing Officer's finding of contempt, based only on a level of "probability," not on "clear and convincing evidence" as articulated in *Cruzan* and in other circuits, has given rise to an irreconcilable conflict with at least two other federal circuits on ***the same*** federal law issue -- i.e., the definition of "clear and convincing evidence" in civil contempt proceedings. *Compare Travelhost*, 68 F.3d at 961 (5th Circuit) *and Quinter*, 671 F.2d at 974 (3d Circuit). Accordingly, the writ should be granted to resolve these opposing circuit court decisions.

II The Court of Appeals Erred as a Matter of Law by Affirming an Administrative Finding of Contempt Based Exclusively on an Incomplete and Defective Tape Recording Created by an Agency Official whom Petitioners Could Not Cross-Examine

The Solicitor General's arguments for why this Court need not review the remaining two Questions Presented are also unconvincing. The FDA met its burden of proving contempt of a court order by "clear and convincing evidence" by relying upon the badly flawed undercover tape recording of an FDA agent, Beverly Ritter, who refused to be cross-examined. The Solicitor General asserts that this issue is too "fact-bound" to be worthy of this Court's review. *See* Opp. Br., at 7. There is, however, no factual issue regarding Petitioners' inability to cross-examine Ms. Ritter, who admittedly activated the tape recording only during selected portions of her visit to the Century Clinic. Nor does (or can) the Solicitor General identify any record evidence other than a flawed interpolation of a single excerpt from the badly compromised tape recording to "support" the Hearing Officer's finding of contemptuous misuse of the LISTEN system device.

Certainly this Court's review is warranted to correct the FDA's refusal to afford Petitioners the basic procedural due process right of confronting their accuser through cross-examination. *See* Pet. Opening Br., at 19-20 (citing Supreme Court cases). The Solicitor General wrongly argues that Petitioners waived their right to cross-examine the FDA agent by signing the Consent Decree *(see* Opp. Br., at 7-8). Yet, the Consent Decree contains no waiver language. *See D.H. Overmyer Co. v. Frick Co.*, 405 U.S. 174 (1972) (waiver of procedural due process rights must be clear, knowing, and voluntary).

To the contrary, Paragraph 10 of the Consent Decree states that the Petitioners "shall have a *full opportunity* to submit written materials on their behalf, and to make an oral presentation to the FDA." Apdx., at 79a ¶ 10 (emphasis added). Accordingly, Petitioners sought to depose agent Ritter for the stated purpose of submitting her transcribed deposition testimony. The deposition testimony of other deposed witnesses was submitted to, and received as record evidence by, the Hearing Officer. Yet, Petitioners were denied this "opportunity" when it came to agent Ritter. Clearly, the Consent Decree provided otherwise. A "full opportunity" to defend oneself against contempt charges certainly includes the right to cross-examination and offer the recorded deposition testimony of one's accuser (indeed, only accuser). *See Consolidation Coal Co. v. United Mine Workers*, 514 F.2d 763, 765 (6th Cir. 1975) ("like any civil litigant, a civil condemner [sic] is . . . clearly entitled to those due process rights, applicable to every judicial proceeding . . . ."). Yet, Petitioners were denied all access to agent Ritter.

The critical importance of this denial cannot be overstated. The contempt finding hangs only on a single excerpt (badly misinterpreted) from agent Ritter's incomplete,

garbled recording. The Solicitor General lamely claims there was additional supporting evidence, asserting that the Hearing Officer "also relied on Petitioners' admission that they failed to collect any of the data necessary to determine whether the LISTEN System device could detect diabetes." *See* Opp. Br., at 7. Petitioners were, however, explicitly instructed by the study Sponsor, in writing, not to collect conductance data during practice sessions with the LISTEN System device. The evidence to which the Solicitor General points affirms (in accordance with all other evidence in the record) that the device was in fact used properly by Petitioners *for practice purposes only*, just as the FDA-approved study Sponsor instructed, and was never used improperly for "diagnostic purposes," as the FDA alleged.

CONCLUSION

For all of the foregoing reasons, and the reasons discussed in the Petitioners' Opening Brief, the petition for a writ of certiorari should be granted.

Dated: February 24, 2000

Respectfully submitted,

Wm. Bradford Reynolds
(Counsel of Record)
Stephen Weissman
COLLIER, SHANNON, RILL
& SCOTT, PLLC
3050 K Street, N.W.
Suite400
Washington, D.C. 20007
(202) 342-8400

Thomas C. Bradley
SINAI, SCHROEDER,
MOONEY
BOETSCH & BRADLEY
448 Hill Street
Reno, NV 89501
(702) 323-5178

Attorneys for Petitioners